

§ 880.2800

device also is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38804, July 25, 2001]

§ 880.2800 Sterilization process indicator.

(a) *Biological sterilization process indicator*—(1) *Identification*. A biological sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor adequacy of sterilization. The device consists of a known number of microorganisms, of known resistance to the mode of sterilization, in or on a carrier and enclosed in a protective package. Subsequent growth or failure of the microorganisms to grow under suitable conditions indicates the adequacy of sterilization.

(2) *Classification*. Class II (performance standards).

(b) *Physical/chemical sterilization process indicator*—(1) *Identification*. A physical/chemical sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor one or more parameters of the sterilization process. The adequacy of the sterilization conditions as measured by these parameters is indicated by a visible change in the device.

(2) *Classification*. Class II (performance standards).

§ 880.2900 Clinical color change thermometer.

(a) *Identification*. A clinical color change thermometer is a disposable device used to measure a patient's oral, rectal, or axillary (armpit) body temperature. The device records body temperature by use of heat sensitive chemicals which are sealed at the end of a plastic or metal strip. Body heat causes a stable color change in the heat sensitive chemicals.

(b) *Classification*. Class I (general controls). The device is exempt from the

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premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38804, July 25, 2001]

§ 880.2910 Clinical electronic thermometer.

(a) *Identification*. A clinical electronic thermometer is a device used to measure the body temperature of a patient by means of a transducer coupled with an electronic signal amplification, conditioning, and display unit. The transducer may be in a detachable probe with or without a disposable cover.

(b) *Classification*. Class II (performance standards).

§ 880.2920 Clinical mercury thermometer.

(a) *Identification*. A clinical mercury thermometer is a device used to measure oral, rectal, or axillary (armpit) body temperature using the thermal expansion of mercury.

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 63 FR 59228, Nov. 3, 1998]

§ 880.2930 Apgar timer.

(a) *Identification*. The Apgar timer is a device intended to alert a health care provider to take the Apgar score of a newborn infant.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice requirements in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

[63 FR 59718, Nov. 5, 1998]

Subparts D-E [Reserved]